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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,022	03/12/2004	Frederick F. VanGoor	VPI/03-103 US	6802

27916 7590 06/26/2006

VERTEX PHARMACEUTICALS INC.
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CAMBRIDGE, MA 02139-4242

EXAMINER

KOSACK, JOSEPH R

ART UNIT PAPER NUMBER

1626

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/800,022	Applicant(s) VANGOOR ET AL.	
	Examiner Joseph Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52, 54, 55 and 83-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52, 54, 55 and 83-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 52, 54-55, and 83-86 are pending in the instant application.

Amendments

The amendment filed on May 15, 2006 has been acknowledged and has been entered into the record.

Election/Restrictions

Applicant elected Group II, claims 49 and 52-84 along with an election of species in the reply filed February 1, 2006 in response to the restriction requirement made on December 9, 2005.

Status of the Claims

In the amendment filed on May 15, 2006 claims 1-51, 53, and 56-82 were cancelled and new claims 85-86 were added. New claims 85-86 are compound claims and have been grouped in Group II of the restriction requirement made on December 9, 2005. Claims 52, 54-55, and 83-86 are pending in the instant application.

Previous Claim Objections

Claims 49, 52-55, and 83-84 were objected to in the action mailed on February 15, 2006 for containing elected and non-elected subject matter. Applicant has cancelled the non-elected subject matter in the amendment filed on May 15, 2006 and the objection is withdrawn.

Claim 83 was objected to in the action mailed on February 15, 2006 for using codes from the specification to identify compounds. Applicant has corrected this informality and the objection is withdrawn.

Previous Claim Rejections - 35 USC § 112

Claim 49 was rejected in the action mailed on February 15, 2006 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant has cancelled the claim in the amendment filed on May 15, 2006 and the rejection is withdrawn.

Claim 84 was rejected in the action mailed on February 15, 2006 under 35 U.S.C. 112, second paragraph as being indefinite. Applicant has amended the claim such that is dependent upon only compound claims and not method of use claims or item of manufacture claims. Therefore, the rejection is withdrawn.

Previous Claim Rejections - 35 USC § 102

Claims 49, 55, and 84 were rejected in the action mailed on February 15, 2006 under 35 U.S.C. 102(b) as being anticipated by Kästner et al. (DE 41 26 543 A1). Applicant has cancelled claim 49 and corrected the dependency of claim 84 in the amendment filed on May 15, 2006. Applicant has also pointed out the proviso at the end of claim 55 specifically excluding the Kästner compound. Therefore, the rejection is withdrawn.

Previous Claim Rejections - 35 USC § 103

Claims 49, 52-55, and 83-84 were rejected in the action mailed on February 15, 2006 under 35 U.S.C. 103(a) as being unpatentable over Kästner et al. (DE 41 26 543 A1).

Applicant has traversed the rejection on the grounds that Kästner et al. do not teach the use of the instant compounds claimed by the Applicant. The Examiner points

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out that the claims are drawn to a product, not a method of use of a product. Therefore, the use of a compound is not a limitation that must be addressed. The requirements for a *prima facie* case of obviousness are provided by teaching the limitations of the claims by the combined teachings of the prior art, providing a motivation to the person of ordinary skill to combine the teachings, and to provide the person of ordinary skill in the art a reasonable expectation of success. The motivation to synthesize a compound in the prior art can be different from the motivation of Applicant to synthesize the claimed compounds as a product is being claimed and not a method of use. Therefore, the *prima facie* case of obviousness stands and the rejection stands on claims 52, 54-55, and 83-84. Claims 49 and 53 have been cancelled in the amendment filed on May 15, 2006 and the rejection of those claims have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

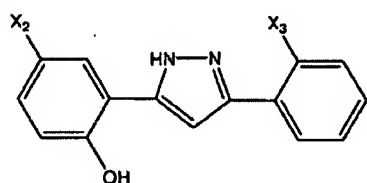
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

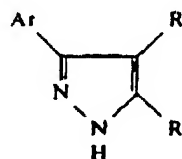
Claims 49, 52-55, and 83-84 rejected under 35 U.S.C. 103(a) as being unpatentable over Kästner et al. (DE 41 26 543 A1).

The instant application cites compounds of the formula



where X₂ is halogen; and X₃ is H, halogen, CF₃, and NO₂.

Determination of the scope and content of the prior art (MPEP §2141.01)



Kästner et al. teach a compound of the formula with substituents as defined. See page 2, line 60 through page 3, line 6.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Kästner et al. do not teach specifically all compounds which fall into the scope of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Kästner et al. teach generally the compounds of the instant invention, including the elected species when Ar is 2-hydroxyphenyl substituted by Cl, R is phenyl substituted by CF₃ and R¹ is hydrogen. See page 2, line 60 through page 3, line 6. Kästner et al also teaches the pharmaceutical composition comprising the compounds. See page 6, lines 40-49.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to follow the synthetic scheme of Kästner et al. and make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Kästner et al. Kästner et al. teach the use of the synthesized compounds to treat psoriasis. See page 6, lines 28-39.

Thus, the claimed invention as a whole was *prima facie* obviousness over the prior art.

The following objections and rejections have been necessitated by the amendment filed on May 15, 2006.

New Claim Objections

Claim 84 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to preceding claims only. See MPEP § 608.01(n).

Claims 85-86 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are materially the same as claim 55.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

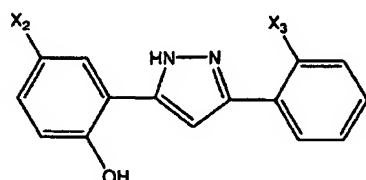
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

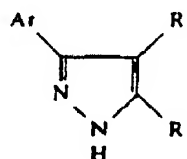
Claims 85-86 rejected under 35 U.S.C. 103(a) as being unpatentable over Käßtner et al. (DE 41 26 543 A1).

The instant application cites compounds of the formula



where X_2 is halogen; and X_3 is H, halogen, CF_3 , and NO_2 .

Determination of the scope and content of the prior art (MPEP §2141.01)



Käßtner et al. teach a compound of the formula with substituents as defined. See page 2, line 60 through page 3, line 6.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Käßtner et al. do not teach specifically all compounds which fall into the scope of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Käßtner et al. teach generally the compounds of the instant invention, including the elected species when Ar is 2-hydroxyphenyl substituted by Cl, R is phenyl substituted by CF_3 and R^1 is hydrogen. See page 2, line 60 through page 3, line 6. Käßtner et al also teaches the pharmaceutical composition comprising the compounds. See page 6, lines 40-49.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to follow the synthetic scheme of Käßtner et al. and make

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the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Kästner et al. Kästner et al. teach the use of the synthesized compounds to treat psoriasis. See page 6, lines 28-39.

Thus, the claimed invention as a whole was *prima facie* obviousness over the prior art.

Conclusion

Claims 52, 54-55, and 83-86 are rejected. Claims 84-86 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

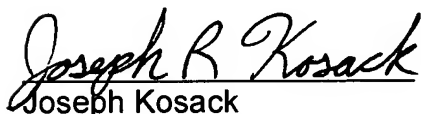
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-

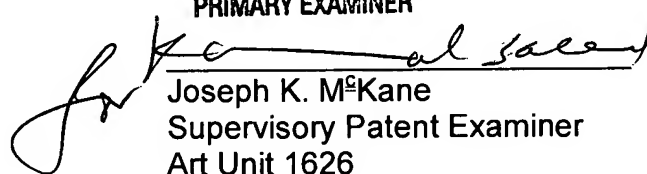
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5575. The examiner can normally be reached on M & W 5:30 A.M.-6:00 P.M. and T & Th 5:30 A.M.-2:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^{re}Kane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Joseph Kosack
Patent Examiner
Art Unit 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Joseph K. M^{re}Kane
Supervisory Patent Examiner
Art Unit 1626